DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 13, 2014

Inovo, Inc.
c/o Mr. Paul Dryden
President
ProMedic, Inc.
24301 Woodsage Drive
Bonita Springs, FL 34134

Re: K141967
Trade/Device Name: PureFill Oxygen Compressor
Regulation Number: 868.5440
Regulation Name: Portable Oxygen Generator
Regulatory Class: II
Product Code: CAW
Dated: October 08, 2014
Received: October 10, 2014

Dear Mr. Dryden:

This letter corrects our substantially equivalent letter of November 7, 2014

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801, please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K141967

Device Name

PureFill Oxygen Compressor

Indications for Use *(Describe)*

The PureFill Oxygen Compressor is indicated to supply pressurized oxygen to fill gas cylinders for the patient's personal ambulatory use. The device is not intended to be life supporting or life sustaining.

Environment of use: - Sub-acute care facilities and home settings

Type of Use *(Select one or both, as applicable)*

XX Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary
Page 1 of 5
8-Oct-14

Inovo, Inc.
401 Leonard Blvd. North
Lehigh Acres, FL 33971 Telephone: 239-643-6577

Official Contact: Ed Brantley, Manager of Engineering

Proprietary or Trade Name: PureFill Oxygen Compressor

Common/Usual Name: Oxygen Compressor

Classification Name: Portable oxygen generator
CAW – 868.5440

Predicate Devices: Gas Transfill – K091191
Home Fill II – K003939

Device Description: The PureFill Oxygen Compressor is designed to accept low pressure (14-30 PSIG) oxygen from existing oxygen concentrators and pressurize the oxygen to 2,000 PSIG to fill patient's portable oxygen cylinders.

Indications for Use: The PureFill Oxygen Compressor is indicated to supply pressurized oxygen to fill gas cylinders for the patient's personal ambulatory use. The device is not intended to be life supporting or life sustaining.

Patient Population: Patients on supplemental oxygen.

Environment of Use: Sub-acute care facilities and home settings.

Contraindications: None

	Predicate Device	**Predicate Device**	**Proposed Device**
Model Name:	**Gas Transfill**	**Venture IOH 200 Home Fill II Complete Home Oxygen System**	**PureFill Oxygen Compressor**
510(k) Number	**K091191**	**K003939**	
Indications	The intended use of the Gas Transfill System is to provide supplemental oxygen to patients and to supply pressurized oxygen to fill gas cylinders for the patient's personal ambulatory use. The device is not intended to be life supporting nor life sustaining. The Transfill System is comprised of a high pressure oxygen compressor and an external oxygen concentrator. The oxygen concentrator provides up to 2LPM of gaseous oxygen to the high pressure oxygen compressor for filling medical oxygen cylinders.	The intended function and use of the Invacare Model IOH 200 Complete Home Oxygen System is to provide supplemental oxygen to patients and to supply pressurized oxygen to fill gas cylinders for the patient's personal ambulatory use.	The PureFill Oxygen Compressor is indicated to supply pressurized oxygen to fill gas cylinders for the patient's personal ambulatory use. The device is not intended to be life supporting or life sustaining. Environment of use: - Sub-acute care facilities and home settings
Environment of Use	Home	Home	Sub-acute care facilities and home settings
Patient Population	Patients on supplemental oxygen	Patients on supplemental oxygen	Patients on supplemental oxygen

Specifications / Features

	Gas Transfill K091191	**Home Fill II K003939**	**Proposed PureFill**
Dimensions (l x w x h)	9” x 20” x 25.5”	16” x 15” x 16”	23" x 8in x 12in
Weight	45 lbs	33 lbs	33 lbs
Sound Level	44 dBA	Unknown	55 dBA
Power Consumption	110W	140W	110W average
Cylinder type	2,000 and 3,000 PSI	2,000 PSI	2,000 PSI
Typical filling time	M6* (2,000 PSI) 1 hr 5 min	M6 (2,000 PSI) 1 to 2 hours and 45 minutes	M4 (2,00 PSI) 55 min M6 (2,000 PSI), 90 min M9 (2,000 PSI) 135 min Typical at 22 psi input pressure
OCD/Regulator type	CGA-870 connection	Unknown	CGA-870 Connection
Delivers Oxygen to patient while filling	Yes	Unknown	Yes
Input Pressure	Not published	14-21 psi	14-30 psig
Input flow	Not published	2 LPM minimum	2 LPM minimum
Compatible Concentrators	EverFlo, EverFlo Q, Millennium M600 and M605 series, and M10	Invacare Platinum 5, 10, XL, and Perfecto2.	Any concentrator that provides: 14-30 PSIG 2 LPM Minimum 93±3% oxygen
Supply Oxygen Concentration	**EverFlo** 93% (+/- 3%) (5 lpm) **Millennium M600/605** 92% (+/- 4%) 5LPM, 94% (+/- 2%) 2LPM **Millennium M10** 92 +/– 4% @ 8-10 LPM 94 +/– 2% @ 3-7 LPM 92 +/– 4% @ 1-2 LPM	**Invacare Platinum 5** All 5LXO2/5LX models 87% to 95.6% at 0.5-5 LPM **Invacare Platinum 10** 87% to 95.6% at 2-10 LPM **Invacare Perfecto2** 87% to 95.6% for flows ranging at 0.5 to 5 LPM	Any concentrator that provides: 14-30 PSIG 2 LPM Minimum 93±3% oxygen
Oxygen Concentration	93% (+/- 3%)	>90%	93±3%

Indicators (alarms)

Alarm / Alert	Gas Transfill	HomeFill II	Propose PureFill
O_2 Concentration	Continuous Green and Yellow with Flashing Red = the device has detected a possible oxygen purity fault (purity is less than 90%) and the oxygen within the cylinder is less than 90%. System continues to fill	Yellow Light = O_2 from concentrator is < 90% (any time after three minute warmup) Cylinder filling stops, will restart when O_2 >90%	No oxygen alarm. Relies on concentrator oxygen monitoring system
Over Pressurization	Not known	Not known	Solid Red FAULT LED and Continuous Audible Alarm. Shut off power to motor. Patient cannot restart unit. Contact your provider > 2200 psig

Substantial Equivalence Rationale

The Drive Inovo PureFill Oxygen Compressor is viewed as substantially equivalent to the predicate devices because:

Indications – The PureFill Oxygen Compressor is indicated to supply pressurized oxygen to fill gas cylinders for the patient's personal ambulatory use. The device is not intended to be life supporting or life sustaining.

This is identical to the predicate – Gas Transfill – K091191, which is intended to provide supplemental oxygen to patients and to supply pressurized oxygen to fill gas cylinders for the patient's personal ambulatory use. The device is not intended to be life supporting nor life sustaining.

This is identical to the predicate – Home Fill II - K003939, which is intended to function and use of the Invacare Model IOH 200 Complete Home Oxygen System is to provide supplemental oxygen to patients and to supply pressurized oxygen to fill gas cylinders for the patient’s personal ambulatory use.

Technology – The PureFill Oxygen Compressor is a 2-Stage Positive Displacement compressor designed to accept low pressure (14-30 PSIG) oxygen from existing oxygen concentrators and pressurize the oxygen to 2,000 PSIG. The high pressure oxygen is used to fill portable oxygen cylinders which are for patients' personal ambulatory use only.

Environment of Use – The PureFill Oxygen Compressor is designed to be used in sub-acute care facilities and home setting. This is identical to the predicates.

Patient Population – Population is defined not by age but by patients on supplemental oxygen. This is identical to predicate – Home Fill II - K003939 and Gas Transfill – K091191.

Performance Specifications – The PureFill has similar specifications to the predicate for pressurization, fill rate and time, ability to connect to several different concentrators with minimum output requirements. The performance specifications are substantially equivalent to the predicates – Home Fill II - K003939 and Gas Transfill – K091191.

Non-clinical Testing
We performed a number of non-clinical tests to demonstrate the safety and efficacy of the PureFill. These tests included:

Materials – The materials utilized are common materials. G95-1 and ISO 10993-1 would categorize the PureFill Oxygen Compressor as:

- External communicating (indirect / gas pathway)
- Mucosa contact
- Permanent duration (> 30 days)

However, mechanical, pressure generating devices often have materials which cannot be tested by the above listed tests. We performed the following tests:

- VOC
- $PM_{2.5}$
- Ozone, CO, and CO_2

Performance Testing – We performed equivalent bench testing, including ES60601-1, IEC 60601-1-2, IEC 61000-6-3, EN55011 CISPR 22, Altitude, Fill rate, Oxygen Pressure Surge Testing, Material Selection and Cleaning of Components, Autogenous Ignition Temperature Test, Acoustic Noise, Audible Acoustic Energy. The PureFill Oxygen Compressor performed as intended in each test. These tests were equivalent to the testing required of the predicates.

Substantial Equivalence Conclusion -
The sponsor has demonstrated through performance testing, design and features, and non-clinical testing that the proposed device and predicate have been found to be substantially equivalent.